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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,246	12/11/2006	Takashi Okada	OKAD3006/GAD	6540
23364 7590 10/01/2010 BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314-1176				
EXAMINER				
SCHULTZ, JAMES				
ART UNIT		PAPER NUMBER		
1633				
MAIL DATE		DELIVERY MODE		
10/01/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/554,246

**Applicant(s)**

OKADA ET AL.

**Examiner**

James (Doug) Schultz, PhD

**Art Unit**

1633

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20, 21, 24-28, 30-34 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) 27, 28, 30-32, 37 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20, 21, 24-26, 33, 34, 36 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 15, 2010 has been entered.

***Status of Application/Amendment/Claims***

Applicant's response filed June 15, 2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed March 17, 2010 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27, 28, 30-32, 37 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. These claims were indicated as withdrawn in the previous action, and on the Office Action Summary (PTO-Form 326), but were inadvertently included in the claim rejections. These claims are in fact withdrawn. Any confusion arising from this error is regretted.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 24, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Samulski et al (U. S. Patent Number 6,410,300).

These claims are drawn to a method for increasing AAV mediated gene transfer comprising administering a histone deacetylase inhibitor to a subject prior to administration of the AAV vector.

Samulski et al. teach a method of facilitating or enhancing attachment of AAV via the use of sodium butyrate to upregulate the expression of cell surface receptors specific for AAV. Samulski et al. teach that this method has the effect of increasing the efficiency of AAV infection into a cell. It was well known in the art at the time of filing that sodium butyrate is a histone deacetylase inhibitor. Furthermore, one of ordinary skill in the art would immediately understand that Samulski's method would only function properly if the histone deacetylase inhibitor were administered prior to the administration of the AAV vector, since the stated purpose of their method is to increase the expression of cell surface receptors specific for AAV.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20, 21, 24-26, 33, 34, 36, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samulski et al. (supra), in view of Kitazono et al., Nakajima et al., and Alisky et al. (the last three of record).

The invention is described above, and further comprises the use of the specific HDAC inhibitor FR901228, and that the cells in which the method is practiced are derived from a subject who has ALS.

Samulski et al. is relied upon as discussed above. Samulski et al. further teach that integrin is a co-receptor for AAV. Samulski et al. does not teach the use of the specific HDAC inhibitor FR901228, or the treatment of cells derived from a subject who has ALS.

Kitazono et al. teach a method of enhancing adenoviral transgene expression in malignant cells treated with the histone deacetylase inhibitor FR901228, corresponding to formula (I) of the instant invention. Kitazono et al. also disclose that they achieved similar results using the histone deacetylase-1 inhibitors sodium butyrate and trichostatin A.

Nakajima et al. teach that FR901228 (i.e. compound I as claimed in at least claim 21) is a potent inhibitor of histone deacetylase and is identical in function to both trichostatin A and trapoxin.

Alisky et al. teaches the use of AAV vectors in delivering genes to cells from subjects having ALS.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the histone deacetylase inhibitor FR 901228 in place of the histone

deacetylase inhibitor sodium butyrate in the method of enhancing AAV gene transfection of Samulski et al. Given that Kitazono teach that administration of a variety of histone deacetylase inhibitors prior to adenoviral vector administration successfully enhances transgene expression, and also that Samulski et al. teach enhancing transgene expression comprising administering a histone deacetylase inhibitor prior to AAV administration, one of ordinary skill in the art would have been motivated to try other known histone deacetylase inhibitors in the methods of Samulski et al. Furthermore, Nakajima et al. teach that FR901228 is a potent inhibitor of histone deacetylase, and is similar in function to N-butyrate, trichostatin and trapoxin. It is prima facie obvious to substitute equivalents known in the art to be useful for the same purpose. Furthermore, it would have been obvious to use cells from a subject having ALS since the use of gene therapy in treating ALS had been previously taught by Alisky et al. Because all compounds and steps were known in the art, one of ordinary skill would have had a reasonable expectation in practicing the claimed invention.

Applicant's arguments with respect to all previously set forth rejections have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James (Doug) Schultz, PhD whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James (Doug) Schultz, PhD/  
Primary Examiner, Art Unit 1633